REMARKS

Claims 1-20 are pending in this application. Claims 2-9 and 11-13 are amended to correct various informalities, as suggested by the examiner. Claims 10 and 14-20 are withdrawn by the examiner. This Office Action is discussed below:

Election/Restriction:

Aplicants elected Group I and of the species "APT3820" [bis-myristoyl-KSSKSPSKKDDKKPGDC] (SEQ ID NO: 8). Only claims 1-9 and 11-13 are examined, because claims 10, 14-20 are withdrawn by the examiner as drawn non-elected group/species, as set forth by the examiner. The elected species was found free of the prior art, therefore the examiner expanded the search to encompass other peptides from claim 11, such as the species bis-myristoyl-GSSKSPSKKKKKKPGDC (SEQ ID NO: 2).

Claim Objection:

Claims 3-6, 8-9 and 12-13 are amended to overcome the examiner's objection concerning various informalities.

Written Description Rejection:

On pages 3-7 of the Office Action, the examiner rejects claims 1-9 and 11-13 under 35 U.S.C. 112, first paragraph, allegedly for failing to comply with the written description requirement. The examiner believes that the claims are broader than what is disclosed in the specification and the disclosure does not provide sufficient examples.

The examiner asserts that the term "membrane binding elements with a low membrane affinity" is a broad generic statement. The examiner also asserts that the specification does not provide sufficient variety of species to reflect the variance in the

genus. The examiner agrees that the elements having a size of <5kDa having basic amino acid elements and two lipophilic elements are disclosed in the specification (see specification, for example, page 2, 5th paragraph). The examiner also agrees that the specification does provide examples of what qualify as compounds of the claimed invention (see for example, page 6, Table 1, page 7; pages 12-28).

However, the examiner asserts that these are not adequately described and/or represented in the examples and are limited to a few examples such as synthesis and purification of a few bis-myristolylated peptide conjugates drawn to small peptides, a conjugate with CD59, a few anti-hemolytic and anti-complement activity assays and further conjugation to SCR1-3.

Applicants respectfully disagree with the examiner and invite the examiner to consider MPEP, which states:

> "Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.
>
> An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).
>
> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).
>
> Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. But

> because only an enabling disclosure is required, applicant need not describe all actual embodiments."

MPEP § 2164.02 (Rev. 6, September 2007) at 2100-196.

As clarified above and as agreed by the examiner, the specification provides working examples and a discloses a number of species. Therefore, the invention is disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In view of the above clarifications, applicants submit that the written description requirement is met and the applicants were in possession of the claimed inventions at the time the application was filed. Accordingly, withdrawal of the written description/enablement rejection is solicited.

Anticipation Rejection:

On pages 7-8 of the Office Action, the examiner rejects claims 1-2, 6-9 and 12-13 under 35 U.S.C. 102(b) allegedly as being anticipated by Smith *et al.* (U.S. Patent No. 6,713,606). The examiner also rejects claims 1 and 6-7 under 35 U.S.C. 102(b) allegedly as being anticipated by Mossakowska *et al.* (U.S. Publication 2003/0064431). The examiner asserts that Smith *et al.* disclose a "modified agent comprising three or more membrane binding elements with low membrane affinity covalently" at column 2, lines 45-51; and Mossakowska *et al.* discloses the same at claim 14, lines 1-4.

Applicants respectfully disagree with the examiner and point out that the examiner has not shown that the cited references disclose each and every element of the claimed method. In this context, applicants refer the examiner to the dictates of the MPEP:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed.

Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986).

See MPEP § 2131 at 2100-67 (Rev. 6, September 2007).

Applicants also refer to the specification (see pages 3-4, for example), which clarifies the surprising discovery that the claimed modified therapeutic agent comprising three or more membrane binding elements has unexpected advantages over the previously known agents. The examiner has not cited to any reference disclosing a "modified therapeutic agent comprising three or more membrane binding elements." Therefore, the cited references do not disclose each and every element as set forth in the claims, accordingly, do not anticipate the claimed invention.

Regarding Mossakowska *et al.* (US 2003/0064431), applicants note that the application was published on April 3, 2003, while the instant application claims priority to GB0220936.9, filed September 5, 2002. The GB application fully supports the claims. See, for example, pages 3-7, including SEQ ID NOS: 2 and 6-10. Therefore, Mossakowska *et al.* is not a prior art against the claimed invention.

In view of the above clarifications, applicants request withdrawal of the anticipation rejection.

Obviousness Rejection:

On page 8 of the Office Action, the examiner rejects claims 1-9 and 11-13 under 35 U.S.C. 103(a) allegedly as being unpatentable over Mossakowska *et al.* (US 2003/0064431).

As mentioned above, Mossakowska *et al.* (US 2003/0064431) application was published on April 3, 2003 while instant application claims priority to GB0220936.9, filed September 5, 2002. Therefore, Mossakowska *et al.* is not a prior art against the claimed invention.

Applicants also invite the examiner to consider the following from the MPEP:

> "A *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (Affidavit evidence which showed that claimed triethylated compounds possessed anti-inflammatory activity whereas prior art trimethylated compounds did not was sufficient to overcome obviousness rejection based on the homologous relationship between the prior art and claimed compounds.); *In re Wiechert*, 370 F.2d 927, 152 USPQ 247 (CCPA 1967) (a 7-fold improvement of activity over the prior art held sufficient to rebut *prima facie* obviousness based on close structural similarity)."

See MPEP § 2144.09 (Rev. 6, September 2007) at 2100-162.

As discussed above, applicants refer to the specification (see pages 3-4, for example), which discusses the surprising discovery, unexpected advantages and superior properties of the claimed modified therapeutic agent over the previously known agents. Therefore, withdrawal of the obviousness rejection is requested.

Double Patenting Rejection:

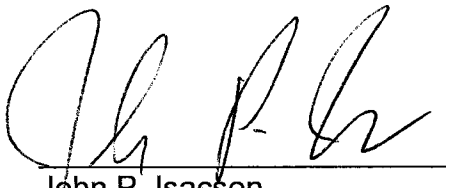
Claims 1-9 and 11-13 are rejected on the ground of non-statutory obviousness-type double patenting allegedly as being unpatentable over claims 1-3, 5-10, and 13-14 of U.S. Patent No. 6,713,606. Applicants will submit a terminal disclaimer upon receipt of the examiner intent of an allowance.

Claims 1, 6-7, and 12-13 also are provisionally rejected on the ground of non-statutory obviousness-type double patenting allegedly as being unpatentable over claims 14-16 and 25 of U. S. Application Serial No. 09/380,682. The applicants submit that since the claims 14-16 and 25 of the U. S. Application Serial No. 09/380,682 (now issued as U. S. Patent No. 6,833,437) have not in fact been patented, this rejection should be withdrawn (*see* MPEP § 822.01).

REQUEST

Applicants submit that claims 1-9 and 11-13 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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